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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/776,010	02/02/01	WILSON G	0179/61248-A

HM22/1019
COOPER & DUNHAM LLP
1185 AVENUE OF THE AMERICAS
NEW YORK NY 10036

EXAMINER	
LI,B	
ART UNIT	PAPER NUMBER
1648	6

DATE MAILED: 10/19/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

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Commissioner of Patents and Trademarks

Office Action Summary	Application N .	Applicant(s)	
	09/776,010	WILSON ET AL.	
	Examin r	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 June 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-29 are pending.

Claim Rejections - 35 USC § 112

Claims 1-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1-2 are vague and indefinite in that the metes and bonds of a transfer factor are not defined. The claims are interpreted in light of the specification, however, since transfer factors can be produced in response to different viruses, bacteria or even tumor, the claims should point out which specific transfer factor is intended in the said claims. Is this transfer factor an antigen specific? Please clarify. This affects the dependent claims 3-12 and 16-29.

Claim 9 is vague and indefinite I that the metes and bonds of a carrier are not defined. The claim is interpreted in light of the specification, however, since there are many kinds of carriers in the art, the claim should point out which carrier is intended in the said claim.

Claims 13-18 are unclear in that the metes and bonds of the "subject" are not defined. The claims are in interpreted in light of the specification, however, specification fails to teach what is the definition of the "subject"? Is a bovine a subject? Or is a human being a subject? Please specify the subject.

Claims 13-18 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: what is the administering dosage and rout of administering and how to measure the clinical parameter in response to the treatment of human herpesvirus-6B transfer factor etc.

Claims 16-18 and 25-27 are vague and indefinite in that the metes and bonds of the abnormalities are not defined. The claims are interpreted in light of the specification; however, the specification fails to teach what is the definition of abnormalities and what is the criterion for determine the abnormal and normal? Please clarify.

The claim 24 is also vague for recitation of a relative word "capable of", because the capability of a compound or composition to perform some function is merely a statement of a

latent characteristic of said compound or composition and said language carries no patenable weight. Therefore, the claims are regarded as indefinite.

Claims 25-27 provides for the use of claims 1 and 2, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 25-27 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 5-13 and 16-29 are rejected under 35 U.S.C. 102(b) as being anticipated by De Vinci et al. (Biotherapy 1996, Vol. 9, pp. 87-90).

DeVinci et al. teach a method for treating patients suffering Chronic Fatigue Syndrome (CFS) with antigen specific transfer factor (TF), which is active against EBV, HHV-6 and CMV. One kind of TF is extracted from spleens of BALB/c mice immunized with EBV, CMV, and HHV-6 live virus, and then subsequently replicated in vitro using human lymphoblastoid cell lines (see entire document). Therefore, the claimed invention is anticipated by the cited prior art.

Claims 1-2, 5-13 and 16-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Ablashi et al. (Biotherapy 1996, Vol. 9, pp. 81-86).

Ablashi et al. teach a method for treating patients suffering Chronic Fatigue Syndrome (CFS) with antigen specific transfer factor (TF), which is active against EBV, HHV-6 and CMV. The TF is extracted from spleens of BALB/c mice immunized wit EBV, CMV, and HHV-6 live virus, and then subsequently replicated in vitro using LDV/7 cells, a B-lymphoblastoid cell line

(see entire document). Therefore, the claimed invention is anticipated by the cited prior art.

Claims 1-4, 10-12 and 16-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilson (U.S. Patent No. 4,816,563).

Wilson et al. teach that antigen specific extracted transfer factor (TF) can be obtained from colostrums or milk secreted by the mammary glad of a suitable lactating mammal, e.g. a cow having immunity to a specific antigen under suitable condition. The FT may then be used to prevent or treat the disease. The TF can be incorporated into edible compositions into pharmaceutical or veterinary composition. The TF may be employed to confer immunity against diseases associated with a specific antigen to which the TF-producing animal is immunized. The said antigen includes the herpetovirodae, such as herpes simplex virus, Newcastle's disease, Marek's disease etc (see abstract, summary of invention and claims 1-28). Therefore, the claimed invention is anticipated by the cited prior art.

Claims 1-2, 5-12 and 16-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilson (U.S. Patent No. 4,610,878).

Wilson et al. teach several methods related to the preparation of antigen specific TF from dialyzed leukocyte extract and an in vitro assay for measuring quantitative parameter related to the clinical usage of TF in regarding to the host cellular immunity against specific antigen, to which the TF-producing animal is immunized (see the entire document). Therefore, the claimed invention is anticipated by the cited references.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. (Patent Nos. 4,816, 563, 4,610,878), Ablashi et al. (Biotherapy, 1996, Vol. 9, pp. 81-86) in view of Challoner et al. (P. N. A. S. 1995, Vol. 92, pp. 7440-7444).

The claimed invention is drawn to a human herpesvirus-6A and human Herpesvirus-6B

antigen specific transfer factor (TF) and method of using the TF for treatment of chronic fatigue syndrome (CFS) and multiple sclerosis as well as to enhance the immunity against the specific infectious agent infection, wherein the HHV antigen specific TF can be isolated from colostrums of a bovid or other immune system component, such as dialyzable leukocyte extract or immune organ lysate or cell or lymphoblastoid cell line extract.

Wilson et al. disclose the method for producing and testing as well as using the antigen specific TF from a colostrums or milk of a bovid (Patent 563), and leukocytes of infected patients (Patent 878), wherein the said TF is used for enhance the cellular immunity against specific antigens to which the TF-producing animal is immunized, such antigens include the large family of herpetoviridae, such as herpes simplex virus, Newcastle's disease, Marek's disease etc. Although Wilson et al. did not teach that the HHV specific TF is used for the treatment of CFS or MS associated with the HHV infection, he clearly teach that the function of the antigen specific TF is to enhance the cellular immunity fro treatment and prevention of the host against the specific infectious agent, to which the TF is specifically produced.

Ablashi et al. teach a method for treating patients suffering Chronic Fatigue Syndrome (CFS) with antigen specific transfer factor (TF), which is active against EBV, HHV-6 and CMV. The TF is extracted from spleens of BALB/c mice immunized wit EBV, CMV, and HHV-6 live virus, and then subsequently replicated in vitro using LDV/7 cells, a B-lymphoblastoid cell line. Because the transfer factor can produce activity cross the species, injection of the isolated TF significantly alleviates the clinical symptom of the patients suffering from CFS caused by HHV6 infection (see entire document). Ablishi et al. differ in that they did not use the FT factor to treat the patients suffering from the Multiple sclerosis caused by HHV-6 A or B infection •

Challoner et al. teach that the HHV-6 B infection is associated with patients suffering with MS. They found that the major DNA binding protein gene of HHV-6 B were detected in 36 out of 37 patients' damaged brain tissue, which is the hall marker of the MS, They suggested that the HHV-6 infection is an etiology or pathogenesis of MS (see abstract).

Therefore, it would have been obvious for a person skill in the art at the time the application was filed to be motivated to combine the teaching from all the references cited above and use the HHV-6 A or B specific TF isolated from either the colostrums of an immunized cow or other immune system component, such as the mice spleen cell or B-lymphoblastoid cells for

treatment of the CFS and MS or in general foe enhancing the immune response for patients suffering from the HHV6 A or B infection without any unexpected results. Hence the claimed invention as a whole is prima facie obvious absence unexpected results.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 8:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li

October 15, 2001

ALI R. SALIMI
PRIMARY EXAMINER